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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,118	10/30/2001	Stanford Mark Moran	BMED-004/01US	8022

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,118	MORAN, STANFORD MARK	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-17,19,20,22,24-33,35-37,40-47,49-54 and 68-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2-17,19,20,22,24-33,35-37,40-47,49-54 and 68-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/15/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/2005 has been entered. An action on the RCE follows.

2. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

3. Claims 5-7, 10, 11, 13, 14, 19, 20, 25-27, 30-33, 38, 40, 49-52, 54, 58 and 74 have been amended. Claims 34 and 48 have been cancelled. Claims 78-83 have been added. Thus, claims 2-17, 19, 20, 22, 24-33, 35, 36, 37, 40-47, 49-54 and 68-73 are pending and under consideration.

4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

5. The Office acknowledges the submission of the IDS dated 6/15/2005.

Claim Rejections - 35 USC § 103, maintained

6. The rejection of claims 2, 3, 8, 10, 10, 14-17, 19, 22, 24, 28, 30, 33-38, 40-47, 49-54, 68-77 under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri and Harper is maintained for reasons of record in the Office Actions dated 18 March 2004

and15 December 2005. Applicants discuss the case law and the legal standards for the obviousness rejection on pages 13 and 14 of the response filed 6/15/2005.

Applicant argues that Sorenson teaches an external, iontophoretic pump and is thus not related to instant invention. Applicant states that Sorenson does not teach a method that uses an internally presented implantable pump that is not externally programmed. Further, Applicant states that the method of Sorenson is intended to provide the patient with an initial high peak level of drug, followed by lower maintenance levels, while the purpose of Applicant's short-term formulation is to find a suitable dose that provides an appropriate level of therapeutic benefit for the patient and enables dose-individualization and the setting of a long-term administration scheme. Applicant states that the reference should be in the field of the inventor's endeavor or reasonably pertinent, while Sorenson's pump is so different as to not fall within the field of endeavor. Applicant also argues that Sorenson discloses a very different device for a very different purpose. Applicant additionally argues that Harper does not provide the necessary motivation to combine the references and that it does not teach a method of administering and adjusting the steps. Applicant argues that Palmeri does not provide the suggestion to combine the references and further that the combination of the three references does not lead to Applicant's invention, but rather to two types of pump and an advanced colorectal carcinoma optimization study. Applicant concludes that the artisan would not look at Sorenson and combine it with the other teachings and that such combination would not teach or suggest every limitation of the instant claims including the newly added limitations to claims 68 and 74.

Applicant's arguments have been fully considered but have not been found to be persuasive. It is also noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Contrary to Applicants assertion that Sorenson does not provide one of ordinary skill in the art with guidance on optimization, and particularly the adjusting and selecting/determining/defining steps in the methods of the invention, as was previously stated on p. 3 of the office action of 18 March 2004, Sorenson was cited as teaching a method of achieving optimal drug levels, including interferons, which is also Applicant's goal (see columns 1 and 2). Furthermore, Palmeri also teaches optimization by selecting and determining the optimal doses interferon for delivery outside the pump mechnism. In addition, Palmeri also discloses short-term formulations administered subcutaneously and adjusting the short-term formulation dosage as appropriate of interferon (see page 328) based on the toxicity etc., thus meeting the limitation of claim 68. This determination will allow for the long-term administration as taught by Sorenson. In response to applicant's argument that there is no motivation provided by Harper or Palmeri to combine the references, as was stated in the previous Office action, Palmeri teaches a problem that can be solved by the method of Sorenson and Harper teaches pumps that are useful for that method. Thus it would be obvious to the artisan of ordinary skill to combine them, resulting not in merely the combination of two pumps and a study but in a method of altering drug levels to optimize doses by administering a first formulation followed by a second formulation

using an internal pump. Alternatively, administering the short-term formulations outside the pump mechanism to determine the suitable dosages for long-term administration and later administering the long-term formulations using an internal pump. As indicated in the Office Action of 15 December 2004, the courts have held that:

> Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY 1979); and In re Burckel 201 USPQ 67 (CCPA 1979).

and

> In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968).

and

> It is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Contrary to Applicants assertion that one following the Sorenson teachings may be inclined to rapidly administer a drug, it teaches a method of optimizing interferon doses in which a first level and then a second level is given. In addition, Applicants asserts that one following the Sorenson would not, however, administer a short-term formulation and make adjustments and selections for a later administered, dose-optimized long term formulation. However, as indicated previously, Palmeri teaches a need for such optimization and Harper teaches a pump that is useful for such

optimization. Thus Sorenson, Palmeri, and Harper in combination suggests to the artisan of ordinary skill a method of treatment that optimizes interferon doses by administering a first level and then administering a second level, using an internal pump at meet all the limitations of the instant invention. Applicants also argue one following Sorenson would not, however, administer a short-term formulation and make adjustments and selections for a later administered, dose-optimized long-term formulation. Further, Applicants argue that the instant invention has the advantage of minimizing or eliminating "the need to alter the rate or change the dose-rate of the dug once long-term dosing has commenced with a long-term delivery system." Applicant appears to differentiate Sorenson reference from teaching that of instant invention it is the combined teaching that makes the instant invention obvious over Sorenson in view of Palmeri and Harper. Specifically, Palmeri teaches the individualizing the doses for short-term and subsequent long-term administration.

7. The rejection of claims 4-7, 9, 12, 13, 20, 25-27, 29, 32, and 33 under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri and Harper and further in view of Johnson is maintained for reasons of record in the office action of 18 March 2004 and15 December 2005. The rejection is also applied to newly presented claims 78-83.

Applicant argues that obviousness rejection is improper with respect to independent claims, particularly due to the failure of the art to teach each and every limitation of the claims. Applicant's arguments have been fully considered but have not been found to be persuasive. For the reasons set forth above, the combination of

Sorenson, Palmeri, and Harper would lead the artisan of ordinary skill to Applicant's invention. Johnson teaches the diseases and interferons (including omega) within the scope of the claims and further teaches a need for optimization (see p. 4 of the office action of 18 March 2004). In addition Sorenson also discloses long-term administration (up to 12 months), limitations present in claims 80-81 (see column 7, lines 50-55). Therefore, claims 4-7, 9, 12, 13, 20, 25-27, 29, 32, 33 and 78-83 are unpatentable over Sorenson in view of Palmeri and Harper and further in view of Johnson is maintained

8. The rejection of claims 11 and 31 under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri, Harper, and Johnson and further in view of Kwan is maintained for reasons of record in the office action of 18 March 2004 and 15 December 2004.

Applicant argues that the disclosure of Kwan fails to address the shortfalls of the other references and further in combination with Sorenson, Harper, and Palmeri references fails to make obvious claims 11 and 31 because even if motivation to combine the references were to be found, all claim limitations are not met in the independent claims and Kwan adds nothing to supply the missing limitations. Specifically, Applicants argue that claim a limitation including omega interferon in the long-term formulations is not taught by Palmeri reference and thus claims are non-obvious.

Applicant's arguments have been fully considered but have not been found to be persuasive. For the reasons set forth above, there are no shortfalls in the combination of the other references. The use of omega interferon is addressed in Johnson and it is

the combination of the teaching which render the claims obvious over the prior art. Kwan was cited as teaching compositions with advantageous formulations; it would be *prima facie* obvious to the artisan of ordinary skill to use them because they are in fact advantageous: they retard microbial growth. Therefore, claims 11 and 31 are unpatentable over Sorenson in view of Palmeri, Harper, and Johnson and further in view of Kwan is maintained.

Applicants conclude by again asserting that the references do not teach all the limitations of the instant inventions including separate mode of administration for short and long term administrations, concluding that Sorenson and Harper references do not contemplate administration of short and long-term formulations via different modes of administration. As addressed above Palmeri indeed administers interferon subcutaneously for short-term purposes. Therefore, instant inventions are *prima facie* obvious over prior art of record.

9. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 09/05

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER